



PATENT
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IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/518,759 Confirmation No.: 2877
First Named Inventor : Takekuni NAKAMA
Filing Date : December 21, 2004
Title : AGENT FOR TREATMENT OF PEMPHIGOID
TC/Art Unit : 1646
Examiner: : Bruce D. HISSONG, Ph.D.
Docket No. : 58777.000017
Customer No. : **21967**

MAIL STOP AMENDMENT

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL RESPONSE

Sir:

Applicant respectfully submits the following partial translation of "JSICR News Letter, No. 1, March 18, 1996, Japanese Society of Interferon and Cytokine Research (JSICR)" for the convenience of the Examiner. Applicant believes that no fees are required for the submission of this Supplemental Response. However, in the event that the USPTO requires any fees to enter this Supplemental Response or to maintain the present application pending, please charge such fee to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,
HUNTON & WILLIAMS LLP

Dated: January 3, 2007

By:


Robert M. Schulman
Registration No. 31,196

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W. Suite 1200
Washington, DC 20006
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

Christopher J. Nichols, Ph.D.
Registration No. 55,984



[Partial Translation]

"JSICR News Letter, No. 1, March 18, 1996, Japanese Society
of Interferon and Cytokine Research (JSICR)"

[page 6, right column, lines 30-37]

(Domestic Standards)

Although international units (IU) can be indicated for domestic standards in the case of a prior WHO standard, since a domestic standard must be set independently in the case domestic formulation has come first, Japan Reference Units (JRU) are used for the indicated titer. At present, IL-2, TNF α and IFN- γ fall into this category.

[page 7, left column, lines 17-36]

Hu.rec IFN- γ (J-R-8703)(80000 JRU) was pitted against a domestic standard (Gxa01-902-535) by the three firms of Suntory, Shionogi & Co. and Yoken from 1995 to 1996. One firm obtained a value of 1 JRU = 1.4 for 10 measurement cycles (n=50), while another firm obtained a value of 1 JRU = 1.96 for 3 measurement cycles (n=60). Yoken also performed measurements using a system consisting of FL cells, sindbis virus and EMC virus. According to the results obtained from 7 measurement cycles (n=154), although precision during individual measurements was high, values were distributed over a wide range, with 1 JRU = 1.15, 1.46, 1.83, 1.26, 1.95, 1.24 and 1.5 IU. 1 JRU

did not exceed 1.5 IU in the case of using EMC virus. This is probably due to a difference in molecular forms (ratio of the presence of monomers, dimers and trimers) between the WHO standard and the domestic standard. The reproducibility of titer measurement can be said to be high in consideration of the quality control at the two cooperating firms. On the basis of these results, 1 JRU was arbitrarily determined to be equal to 1.5 IU. Although there are still concerns over problems remaining in the future, we would like to believe that this is a reasonable compromise in consideration of international harmonization. What should be noticed in particular here is that existing cytokine standards are ultimately still bioassay standards, and cannot be used in ELISA and other forms of immunoassays as a general rule.